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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,939	08/20/2003	Thomas Gostelow	0119/0024	5393

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT PAPER NUMBER

3771

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/643,939	Applicant(s) GOSTELOW, THOMAS	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In the amendment filed on September 12, 2006, Examiner acknowledges Claims 1, 3-13, 16 and 17 are pending in this application, with Claims 1, 3-5 and 13 having been amended, and Claims 2, 14 and 15 having been cancelled.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 16 and 17** are rejected under 35 U.S.C. 102(b) as being anticipated by Sauer (6,109,264).

3. **As to Claim 16**, Sauer discloses an apparatus wherein the recited method is inherent in the use of the apparatus. Sauer discloses providing a tracheostomy tube (26) loaded on an instrument (10) comprising a hollow needle (41) having a sharp tip, an elongated member (31) extending with in the needle and projecting from the patient end of said needle and an indicator (24) towards a machine end of the instrument for indicating movement of said elongate member relative to said needle; inserting a patient end of the instrument through the neck tissue of the patient and into the trachea until the change in the status of the indicator indicates that the trachea has been penetrated; and sliding said instrument rearwardly relative to said tracheostomy tube (26) to remove said

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instruments and to position said tracheostomy tube in the trachea. (Please see Figs. 18-33).

4. **As to Claim 17**, Sauer discloses an apparatus wherein the recited method is inherent in the use of the apparatus. Sauer discloses the tracheostomy tube (26) is loaded on a dilator (30) on said instrument (10) and the method includes the step of advancing said dilator (30) forwardly along said instrument (10) to advance said tracheostomy tube (26) into the trachea and subsequently removing said dilator (30) to leave said tracheostomy tube (26) in position. (Please see Figs. 18-33).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1, 3, 5-11, and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer (6,109,264) in view of Fortune et al. (5,507,279).

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8. **As to Claim 1**, Sauer discloses a medico-surgical instrument (10) for ventilation via the trachea comprising (Fig. 1): a hollow needle (41) having a sharp tip adapted to penetrate the trachea through neck tissue (Figs. 18-24); an elongated membrane (31) (Figs. 16 and 18-24); a resilient membrane (136) (Figs. 7, 9, and 10); and an indicator (24) towards the rear end of said needle for indicating position of said elongate member relative to said needle so that the user knows that the trachea has been penetrated (Column 8, Lines 60-65). Yet Sauer does not expressly disclose the limitations of the elongated inner member in cooperation with the resilient member. However, at the time the invention was made these elements and their interactions were well known. Specifically, Fortune teaches a medico-surgical instrument used for the placement of a guide wire into the trachea of a patient. (Figs. 9-12). The elongated inner membrane (24) located within said needle (22) such that the member can slide along its length relative to the needle (22), a resilient member (38) adapted to urge said inner membrane forwardly relative to said needle (22), such that a forward end of said inner membrane (24) is located forwardly of said needle tip (30) before use but is displaced rearwardly during passage through the neck tissue by engagement with the tissue and moves forwardly relative to said needle when said trachea is penetrated. (Figs. 1 and 2). Regarding the elongated inner membrane, Fortune teaches the use of the elongated membrane (24) for the purpose of reducing injuries after the initial penetration of the trachea. (Please see Column 4, Lines 56-59). Regarding the cooperation of the resilient member with the elongated inner membrane, Fortune teaches "upon contact with the skin and during needle penetration, the hollow stem (24) is driven into the

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hollow needle by the resistance of the underlying tissue, thereby compressing the first biasing spring (38) and exposing the sharp edges of the needle point (30)" (Column 5, Lines 20-25). Essentially, Fortune teaches the use of resilient member in combination with the elongated inner membrane for the purpose of preventing unintentional needle puncture. (Column 5, Lines 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the needle portion improvements of Fortune for the purpose of providing additional safety measures to protect the patient and user from harm.

9. **As to Claim 3**, Sauer discloses a medico-surgical instrument comprising all the limitations recited in **Claim 3**. Specifically, Sauer discloses a dilator (30) with a tapered patient end mounted on said needle (41), and wherein said tracheostomy tube is mounted on an outside of the dilator with a tapered end of the dilator projecting from a patient end of said tracheostomy tube. As seen in Figures 1 and 32, the location of the inflatable dilator (30) can be seen in contrast to the needle (41) and the tracheostomy tube (26). The modifications of Fortune as previously discussed in **Claim 1**, were incorporated for the purpose of preventing unintentional needle puncture. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the needle portion improvements of Fortune for the purpose of providing additional safety measures to protect the patient and user from harm.

10. **As to Claim 5**, Sauer discloses a medico-surgical instrument comprising all the limitations recited in **Claim 5**. Specifically, Sauer discloses a tracheostomy tube having

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a cuff (28). The modifications of Fortune as previously discussed in **Claim 1**, were incorporated for the purpose of preventing unintentional needle puncture. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the needle portion improvements of Fortune for the purpose of providing additional safety measures to protect the patient and user from harm.

11. **As to Claim 6**, Sauer discloses a medico-surgical instrument comprising all the limitations recited in **Claim 6**; yet does not expressly disclose the inner member is hollow and provides a gas passage along said member. However at the time the invention was made, the use of a hollow inner member was well known. Specifically, Fortune teaches the inner member (24) is hollow for the purpose of facilitating the upward passage of the guide-wire (18) through the trachea of the patient. (Fig. 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the hollow inner membrane for the purpose of assisting the user in the proper placement of the instrument into the patient. Moreover, Applicant has not asserted that the specific structural limitations of the inner member recited provides a particular advantage, solves a stated problem or serves a purpose, thus the use of these structural limitations lacks criticality in their design.

12. **As to Claim 7**, Sauer discloses a medico-surgical instrument comprising all the limitations recited in **Claim 7**; yet does not expressly disclose the inner member is closed at its patient end and opens through a side opening adjacent to the patient end.

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However, at the time the invention was made the recited structural limitations were well known. Specifically, Specifically, Fortune teaches the inner member (24) being closed on the patient end up open on the side opening. As seen in Figure 3, the guide-wire (18) is directed out of the inner member (24) on a side opening adjacent to the patient end. Fortune teaches this structural positioning of the inner member (24) enables the guide-wire (18) to be angled downward in the trachea for proper placement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the hollow inner membrane for the purpose of assisting the user in the proper placement of the instrument into the patient. Moreover, Applicant has not asserted that the specific structural limitations of the inner member recited provides a particular advantage, solves a stated problem or serves a purpose, thus the use of these structural limitations lacks criticality in their design.

13. **As to Claim 8**, the device of Sauer as modified by Fortune comprising all the limitations recited in **Claim 8**, but does not expressly disclose two side openings in the inner membrane. At the time the invention was made, the use of side openings or Murphy's eyes were well known in respiratory tubing devices for the purpose of providing additional ventilation means should the distal portion of the respiratory tubing become blocked. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate multiple side openings in respiratory tubing devices as the Applicant has done. Moreover, Applicant has not asserted that the specific structural limitations of the inner member recited provides a

particular advantage, solves a stated problem or serves a purpose different from that of providing an additional ventilation means, thus the use of these structural limitations lacks criticality in their design.

14. **As to Claim 9**, the device of Sauer as modified by Fortune comprising all the limitations recited in **Claim 9**, but does not expressly disclose a longitudinally elongated side opening. At the time the invention was made, the use of side openings or Murphy's eyes were well known in respiratory tubing devices for the purpose of providing additional ventilation means should the distal portion of the respiratory tubing become blocked. Furthermore, the design of a longitudinally elongated side opening would enable higher volumes of gas to be passed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate multiple side openings in respiratory tubing devices as the Applicant has done.

Moreover, Applicant has not asserted that the specific structural limitations of the inner member recited provides a particular advantage, solves a stated problem or serves a purpose different from that of providing an additional ventilation means, thus the use of these structural limitations lacks criticality in their design.

15. **As to Claim 10**, Sauer discloses a medico-surgical instrument comprising all the limitations recited in **Claim 10**; with the exception of a coupling toward the machine end of the inner member by which as may be supplied. However, at the time the invention was made a coupling device for the inner member was well known. Specifically, Fortune teaches the use of a coupling member (64) for the purpose of providing aspiration means and holding the guide-wire to the instrument to assist in providing

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additional support and control during tracheal penetration. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include a coupling member as taught by Fortune to provide a control means to assist in the penetration of the patient's tracheal tissue.

16. **As to Claim 11**, Sauer discloses a medico-surgical instrument comprising all the limitations recited in **Claim 11**. Specifically, Sauer discloses a visual indicator (24), which inflates and deflates during the placement of the needle tip into the trachea of the patient. (Column 8, Lines 61-65). The modifications of Fortune as previously discussed in **Claim 1**, were incorporated for the purpose of preventing unintentional needle puncture. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the needle portion improvements of Fortune for the purpose of providing additional safety measures to protect the patient and user from harm.

17. **As to Claim 13**, Sauer discloses a medico-surgical instrument (10) for ventilation via the trachea comprising (Fig. 1): a hollow needle (41) having a sharp tip adapted to penetrate the trachea through neck tissue (Figs. 18-24); an elongated membrane (31) (Figs. 16 and 18-24); a spring (136) (Figs. 7, 9, and 10); and an indicator (24) towards the rear end of said needle for indicating position of said elongate member relative to said needle so that the user knows that the trachea has been penetrated (Column 8, Lines 60-65). Further Sauer discloses a dilator (30) and a tracheostomy tube (26). Regarding the dilator, Sauer discloses a dilator (30) with a tapered patient end mounted on said needle (41), and wherein said tracheostomy tube is mounted on an outside of

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the dilator with a tapered end of the dilator projecting from a patient end of said tracheostomy tube. As seen in Figures 1 and 32, the location of the inflatable dilator (30) can be seen in contrast to the needle (41) and the tracheostomy tube (26). Regarding the tracheostomy tube, Sauer discloses the tracheostomy tube (26) extending along an outside of said needle (41) so that said needle (41) can be removed to leave the tracheostomy tube in the trachea after penetration of the trachea. (Figs. 32 and 33). Yet Sauer does not expressly disclose the limitations of the elongated inner member in cooperation with the resilient member. However, at the time the invention was made these elements and their interactions were well known. Specifically, Fortune teaches a medico-surgical instrument used for the placement of a guide wire into the trachea of a patient. (Figs. 9-12). The elongated inner membrane (24) located within said needle (22) such that the member can slide along its length relative to the needle (22), a resilient member (38) adapted to urge said inner membrane forwardly relative to said needle (22), such that a forward end of said inner membrane (24) is located forwardly of said needle tip (30) before use but is displaced rearwardly during passage through the neck tissue by engagement with the tissue and moves forwardly relative to said needle when said trachea is penetrated. (Figs. 1 and 2). Regarding the elongated inner membrane, Fortune teaches the use of the elongated membrane (24) for the purpose of reducing injuries after the initial penetration of the trachea. (Please see Column 4, Lines 56-59). Regarding the cooperation of the resilient member with the elongated inner membrane, Fortune teaches "upon contact with the skin and during needle penetration, the hollow stem (24) is driven into the hollow needle by the

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resistance of the underlying tissue, thereby compressing the first biasing spring (38) and exposing the sharp edges of the needle point (30)" (Column 5, Lines 20-25).

Essentially, Fortune teaches the use of resilient member in combination with the elongated inner membrane for the purpose of preventing unintentional needle puncture. (Column 5, Lines 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sauer to include the needle portion improvements of Fortune for the purpose of providing additional safety measures to protect the patient and user from harm.

18. **Claim 4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer (6,109,264) in view of Fortune et al. (5,507,279) further in view of Toye (6,382,209).

19. **As to Claim 4**, the device of Sauer as modified by Fortune is discussed above, yet fails to expressly disclose the tracheostomy tube having helical reinforcement. However, at the time the invention was made helical reinforcement of the tracheostomy tubes was well known. Toye teaches the use of wire coil (34) inside the tracheostomy tube for the purpose of increasing airflow and reducing airway resistance. (Column 5, Lines 23-32). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Sauer and modified by Fortune to include helical reinforcement in the tracheostomy tube for the purpose of preventing collapse of the airway.

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20. **Claim 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer (6,109,264) in view of Fortune et al. (5,507,279) further in view of Yoon (5,423,760).

21. **As to Claim 12**, the device of Sauer as modified by Fortune is discussed above. As taught by Fortune, the guide-wire (18) maybe painted in multiple colors to assist the user in the placement of the guide-wire. (Column 3, Lines 44-45). However, still the device of Sauer as modified by Fortune does not expressly disclose the visual indicator to be a colored flag movable behind a transparent window. However the use of a colored flag indicator was well known at the time the invention was made. Specifically, Yoon teaches a medico-surgical device for the placement of a cannula into the trachea of a patient. Yoon teaches the coloring of a needle with multiple colors at specific points along the needle for the purpose of observing the distance traveled through the transparent hub. (Column 8, Lines 35-38 and Column 9, Lines 8-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Sauer as modified by Fortune to include a transparent window to allow for visual inspection of the needle position to protect against unintentional puncturing of the tracheal wall.

Response to Arguments

22. Applicant's arguments filed September 12, 2006 have been fully considered but they are not persuasive. Applicant argues the prior art made of record and used in the rejection of the pending claims does not suggest a needle that is urged resiliently forward, does not mention the hub of the needle to be transparent, nor provides visual

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indication of the device. However, the prior art made of record does satisfy the pending claim language as currently written. Upon puncturing of the skin, the resilient means would be expanded from a compressed state, as the resistance of the skin would be decreased. Regarding the hub of the needle to be transparent, Applicant has not recited a claim limitation requiring the hub of the needle to be transparent. Regarding the visual indication, element (24) provides visual indication to the usage of the device. Therefore, Applicant's arguments are not commensurate with the scope of the claims and thus the arguments are deemed not persuasive.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

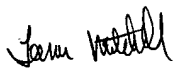
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

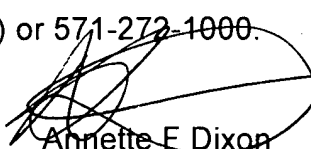
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


TEENA MITCHELL
PRIMARY EXAMINER


Annette F. Dixon
Examiner
Art Unit 3771
November 21, 2006